

CLAIMS

Sub B1 > 1. A rapidly disintegrating tablet of the type designed to disintegrate in the mouth on contact with saliva in less than 5 30 seconds, forming an easy-to-swallow suspension, which contains an active substance in the form of coated microcrystals or microgranules, and a mixture of excipients including at least one disintegrating agent, a soluble agent and a lubricating agent, wherein the lubricating agent is in powder form and at 10 least a major amount of it is distributed on the tablet surface, and that its friability, measured as specified in the French Pharmacopoeia (10th Edition, V.5.1 - Friability of Tablets, January 1993), is less than 1 %, and preferably less than 0.5 %, whereby said tablet can be packaged by standard processes and 15 has the required and adequate hardness to enable it to be removed with ease from the blister pack in which it is packed, by perforating the seal thereof by pushing the tablet, with a substantially reduced risk of the tablet breaking during removal.

20 2. Tablet in accordance with Claim 1, wherein its largest dimension is greater than 5 mm, preferably greater than 17 mm, and capable of reaching 25 mm.

Sub A1 3. Tablet in accordance with Claim 1 or Claim 2, wherein the lubricating agent is selected from among the 25 pharmaceutically acceptable lubricating agents which have a melting point of at least 35°C, and preferably higher than 50°C.

4. Tablet in accordance with one of Claims 1 to 3, wherein the lubricating agent is selected from the group including magnesium stearate, sodium stearyl fumarate, stearic 30 acid and micronized polyoxyethylene glycol.

5. Tablet in accordance with one of Claims 1 to 4, wherein the lubricating agent is magnesium stearate.

6. Tablet in accordance with one of Claims 1 to 5, wherein the quantity of lubricating agent is in the range 0.2 to 10 parts per 1000 (weight of lubricating agent / total weight of tablet), and is preferably in the range 3 to 6 parts per 1000 (weight of lubricating agent / total weight of tablet).

7. Tablet in accordance with one of Claims 1 to 6, wherein the lubricating agent has a particle size distribution such that its constituent particles adhere to a surface when sprayed thereupon, preferably less than 30 microns and more preferably still, less than 10 microns.

8. Tablet in accordance with one of Claims 1 to 7, wherein the disintegrating agent is selected from the group including in particular cross-linked sodium carboxymethylcellulose, known in the industry as croscarmellose, crospovidone and their mixtures.

9. Tablet in accordance with one of Claims 1 to 8, wherein the mixture of excipients may include a permeabilising agent, a solubilising agent, sweeteners, flavors and coloring agents.

10. Tablet in accordance with one of Claims 1 to 9, which is designed to be packaged in blisters composed entirely of aluminum, which may in addition include a cover of a plastic material which is to be torn off before opening.

11. Process for the production of a tablet in accordance with one of Claims 1 to 10, wherein the process involves the following sequence of steps:

- choosing, firstly, an active substance in the form of coated microcrystals or microgranules, and secondly, a set of excipients including a disintegrating agent, a soluble agent, as well as a lubricating agent;

- mixing the active substance and the excipients with the exception of at least a major amount of the lubricating agent;

5 *AT* - feeding a quantity of this mixture necessary to form a tablet into the cavity of a compression device within which the mixture is to be compressed and onto the walls of which the necessary quantity of lubricating agent has been applied in advance;

- compressing the mixture and ejecting the tablet formed.

*Sub B3* 12. Process in accordance with Claim 11, wherein the compression forces are in the range 3 kN to 50 kN, preferably in the range 4 kN to 40 kN, or more preferably still, in the range 5 kN to 25 kN.

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*add B4*